

MAR 21 1997

8 3 8 6 '97 AUG 12 AM 10:05

Mr. Curtis Jacquot
Pacific BioLogic, Inc.
P.O. Box 520
Clayton, California 94517-0520

Dear Mr. Jacquot:

This is in response to your letter to the Food and Drug Administration (FDA) dated March 12, 1997, in which you submitted revised text for a product brochure that describes the intended use of a number of dietary supplements that your firm intends to market.

In a previous letter to your firm dated January 14, 1997, we explained that section 403(r)(6) of the act makes clear that a claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases may not be made under the authority of that section. Certain statements contained in the text you submitted suggest that RESIST and PRE COLD PLUS are intended for one of these purposes.

RESIST is promoted for use in conditions when immune function can be suppressed or compromised, "particularly those that impact bone marrow and the production of white blood cells" and can be used except during "flair-ups of symptoms." In addition, the text refers potential users of the product to a book entitled "Immune Power - A Comprehensive Treatment Program for HIV." Taken together, these claims suggest that the product is intended to prevent, mitigate or treat persons infected with the HIV virus.

The product PRE COLD PLUS is promoted for use "when a particular virus or bacteria is present and strong enough, it invades our system and begins to manifest symptoms of illness." This claim suggests that the intended use of this product is to treat, prevent or mitigate the symptoms of bacterial and viral infections.

These claims on the label or in the labeling of your products evidence that these products are intended to prevent, cure, treat, or mitigate disease and that the products are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 54

Page 2 - Mr. Curtis Jacquot

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals

cc:

HFA-224 (w/incoming)

HFD-310

HFR-PA140

HFS-22 (CCO)

HFS-450 (r/f)

HFS-456 (r/f, Moore w/cpy incoming)

f/t:HFS-456:RJMoore:rjm:3/19/97:DocName:51631.OSN:Disc21



Pacific BioLogic
PO Box 520
Clayton, CA. 94517-0520
(510) 673-2967
(510) 673 2966 fax

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONAL SERVICES-450

'97 MAR 18 10:43
March 12, 1997

Department of Health & Human Services
James T. Tanner, Ph.D., Acting Director
Food and Drug Administration
200 C Street, S. W. HFS-456
Washington, DC 20204

re: Your letter of January 14, 1997

Dear Mr. Tanner:

First off, may I apologize to you for letting our file grow even one letter larger. As you can imaging, we are trying to say the maximum and yet stay within the guidelines the FDA has set for our industry. Thank you for working with us on this as we need to print more copies of our catalog soon and I want to make sure it is right before we do.

Some clarification in ownership of Pacific BioLogic Inc. I purchased the assets of the company and it is now called Pacific BioLogic Co. Still the same products, however I will be your new contact with the firm. Our mailing address has changed as you can see by the letterhead.

I need to address the product descriptions of RESIST and PRE COLD PLUS. May I submit the following:

RESIST

Applications: To supplement the diet when following a total dietary and lifestyle program which is intended to strengthen and support the body's own defense mechanisms.

RESIST is a very versatile tonic and is considered slightly "sweet and warm" (as defined by Traditional Chinese Medicine). It can be used by a wide variety of individuals in different states of health. Most professionals use RESIST when creating programs which are intended to balance the diet when strengthening the body and its own defense mechanisms.

Immune function can be suppressed or compromised through poor nutrition or malabsorbtion of nutrients. Other factors can also effect immune function - particularly those that impact bone marrow and the production of white blood cells. Many drugs and chemicals have been shown to have this effect, particularly chemotherapy agents and many popular antiviral drugs. Even people who do not have any of the above mentioned conditions can experience poor immune

5/631

function through dietary deficiencies or other lifestyle factors such as excess physical and emotional stress. RESIST has been used as part of the "Comprehensive Healing Program for HIV Research" since 1988 by Dr. Jon Kaiser, author of Immune Power – A Comprehensive Treatment Program for HIV. Dr. Kaiser goes into considerable detail on how dietary and lifestyle changes may effect the immune function.

Recommendations: Take 2 – 4 Capsules 2 – 3 times per day on an empty stomach as a dietary supplement. RESIST is best used in conjunction with RESIST 2 in daily rotation. Reduce or discontinue use of RESIST during flair-ups of symptoms or during illnesses such as colds and flu.

PRE COLD PLUS

Applications: To supplement the diet when following a total dietary and lifestyle program which is intended to strengthen and support the body's own defense mechanisms.

PRE COLD PLUS is a unique design which is considered to be a mild tonic but also contains significant clearing components (as defined by Traditional Chinese Medicine). There are two forces that continually challenge each other in the human body. One is the constant onslaught of bacteria and virus germs. The other is our body's defense system that attempts to resist these invasions.

When our body's defense system falters due to fatigue, getting chilled, and other contributing factors which lower our resistance to disease, and the particular virus or bacteria is present and strong enough, it invades our system and begins to manifest symptoms of illness.

Recommendations: Take 2 – 4 Capsules 2 – 3 times per day. Use as early as possible when extra dietary support is desired. If greater dietary support is needed then Cold Free 1 Plus is preferred after the first 48 hours.

Thank you for working with us so we may be in compliance with the FDA standards. I will send you our updated catalog before we publish it.

All the best,



Curtis Jacquot
Pacific BioLogic